K 082446

OCT 15 2008

BIOMET®
MANUFACTURING CORP.

510(k) Summary

Preparation Date: October 7, 2008

Applicant/Sponsor: Biomet Manufacturing Corp.

Contact Person: Becky Earl

Proprietary Name: Biomet® Metal-on-Metal Hip Systems—Expanded Contraindications

Common Name: Hip prosthesis, metal-on-metal articulation

Classification Name: Class III (Preamendment), 21 CFR §888.3330, KWA
- KWA- Hip joint metal/metal semi-constrained, with uncemented acetabular component prosthesis

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
Metal-on-Metal Acetabular System—K993438 (Biomet, Inc.)
M2a™ 28mm RingLoc™ Liner—K002379 (Biomet, Inc.)
M2a™ 32mm Taper System—K003363 (Biomet, Inc.)
M2a™ Acetabular System—K011110 (Biomet, Inc.)
M2a-Magnum™ System—K042037 (Biomet, Inc.)
TaperLoc® 12/14 Femoral Components and One-Piece Modular Heads—K043537 (Biomet, Inc.)
M2a Magnum™ 12/14 Taper Inserts and One-Piece Modular Heads—K061423 (Biomet, Inc.)
M2a-Magnum™ Tri-Spike™ Acetabular Component—K062995 (Biomet, Inc.)

Device Description:
The systems consist of acetabular cups, femoral heads, and adapters and inserts. The Co-Cr-Mo head articulates with Co-Cr-Mo.

Indications for Use/Intended Use:
K993438, K011110, K042037, K043537, K061423, K062995:
1. Non-inflammatory degenerative joint disease including avascular necrosis, diastrophic variant, fracture of the pelvis, fused hip, Legg Perthes, osteoarthritis, slipped capital epiphysis, subcapital fractures, and traumatic arthritis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.
5. Revision of previously failed total hip arthroplasty.

Mailing Address:
P.O. Box 587
Warsaw, IN 46581-0587
Toll Free: 800.348.0500
Office: 574.267.6639
Main Fax: 574.267.8137
www.biomet.com

Shipping Address:
56 East Bell Drive
Warsaw, IN 46582

K002379, K003363:

1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Revision procedures where other treatment or devices have failed.
5. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.

Contraindications have been expanded to include patients with chronic renal failure and patients who are pregnant or may become pregnant.

Summary of Technologies:
The technological characteristics (materials, design, sizing, and indications) of the Biomet® Metal-on-Metal Hip Systems—Expanded Contraindications are identical to the predicate devices.

Non-Clinical Testing: Non-clinical laboratory testing is not provided as a basis for substantial equivalence.

Clinical Testing: None provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2008

Biomet Manufacturing Corp.
% Ms. Becky Earl
Regulatory Affairs Specialist
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K082446
Trade/Device Name: Biomet® Metal-on-Metal Systems- Expanded Contraindications
Regulation Number: 21 CFR 888.3330
Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis
Regulatory Class: III
Product Code: KWA
Dated: August 20, 2008
Received: August 25, 2008

Dear Ms. Earl:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

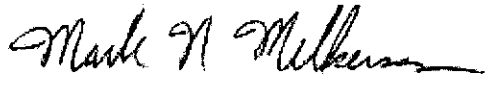
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082446

Device Name: Biomet® Metal-on-Metal Hip Systems—Expanded Contraindications

Indications for Use/Intended Use:

K993438, K011110, K042037, K043537, K061423, K062995:

1. Non-inflammatory degenerative joint disease including avascular necrosis, diastrophic variant, fracture of the pelvis, fused hip, Legg Perthes, osteoarthritis, slipped capital epiphysis, subcapital fractures, and traumatic arthritis.
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K002379, K003363:

1. Noninflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2. Rheumatoid arthritis.
3. Correction of functional deformity.
4. Revision procedures where other treatment or devices have failed.
5. Treatment of non-union, femoral neck fracture, and trochanteric fractures of the proximal femur with head involvement, unmanageable using other techniques.

Prescription Use ___X___ AND/OR Over-The-Counter Use __NO___
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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